Current trials in the field of primary prevention ICD implantation. Potential and challenges - **DILEMMA**

Serge Boveda (Toulouse, FR; Brussels VUB, BE)

sboveda@clinique-pasteur.com

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RATIONALE

ESC European Society of Cardiology
European Heart Journal (2022) 00, 1–130
https://doi.org/10.1093/eurheartj/ehac262
ESC GUIDELINES

2022 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death

Developed by the task force for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death of the European Society of Cardiology (ESC)

Iary Prevention

ICM

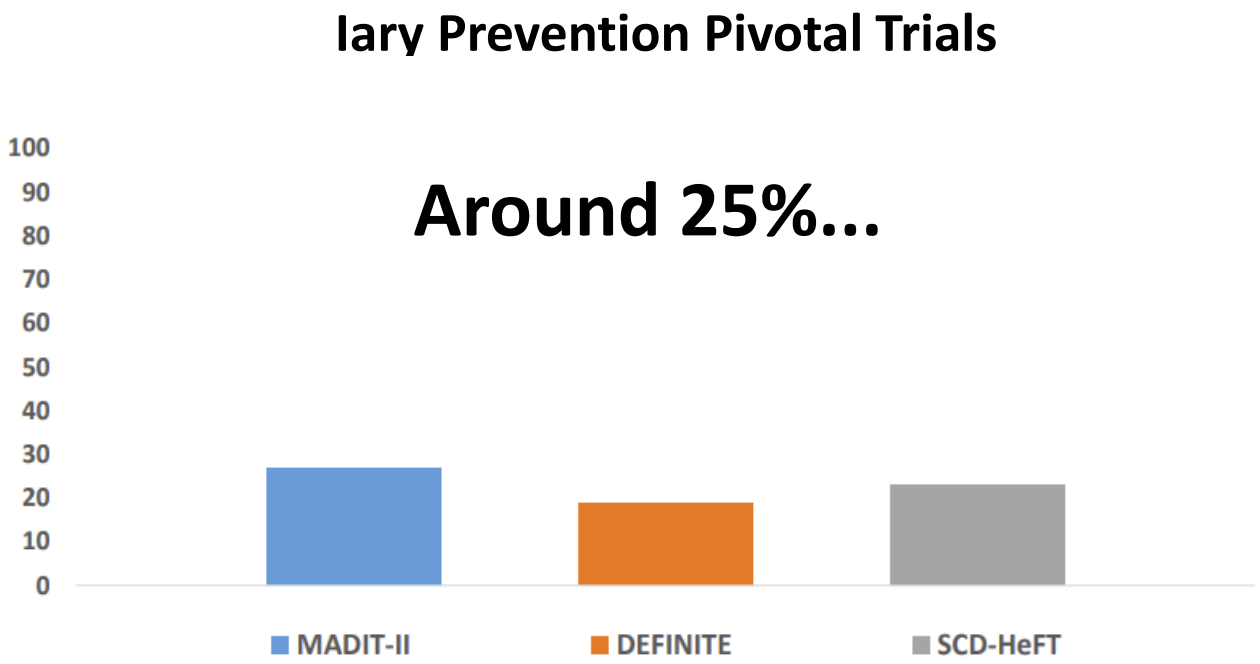
ICD therapy is recommended in patients with CAD, symptomatic heart failure (NYHA class II–III), and LVEF ≤35% despite ≥3 months of OMT.[354,356]	I	A
ICD therapy should be considered in patients with CAD, NYHA class I, and LVEF ≤30% despite ≥3 months of OMT.[354]	IIa	B

NICM

Risk stratification and primary prevention of SCD		
ICD implantation should be considered in patients with DCM/HNDCM, symptomatic heart failure (NYHA class II–III), and LVEF <35% after ≥3 months of OMT.[357,359,635,650]	IIa	A

No « aging » criteria…

The Good: Appropriate ICD therapies



The Bad: ICD complications risk

Subcutaneous or Transvenous Defibrillator Therapy

R.E. Knops, L.R.A. Olde Nordkamp, P.-P.H.M. Delnoy, L.V.A. Boersma, J. Kuschyk, M.F. El-Chami, H. Bonnemeier, E.R. Behr, T.F. Brouwer, S. Kääb, S. Mittal, A.-F.B.E. Quast, L. Smeding, W. van der Stuijt, A. de Weger, K.C. de Wilde, N.R. Bijsterveld, S. Richter, M.A. Brouwer, J.R. de Groot, K.M. Kooiman, P.D. Lambiase, P. Neuzil, K. Vernooy, M. Alings, T.R. Betts, F.A.L.E. Bracke, M.C. Burke, J.S.S.G. de Jong, D.J. Wright, J.G.P. Tijssen, and A.A.M. Wilde, for the PRAETORIAN Investigators*

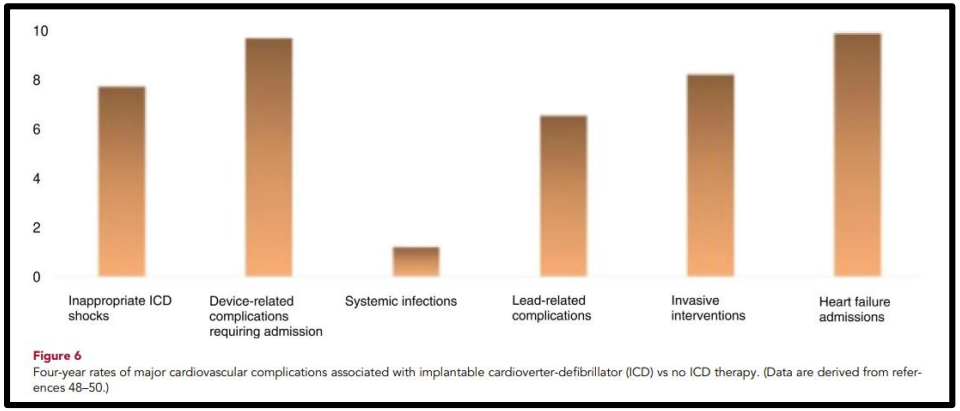
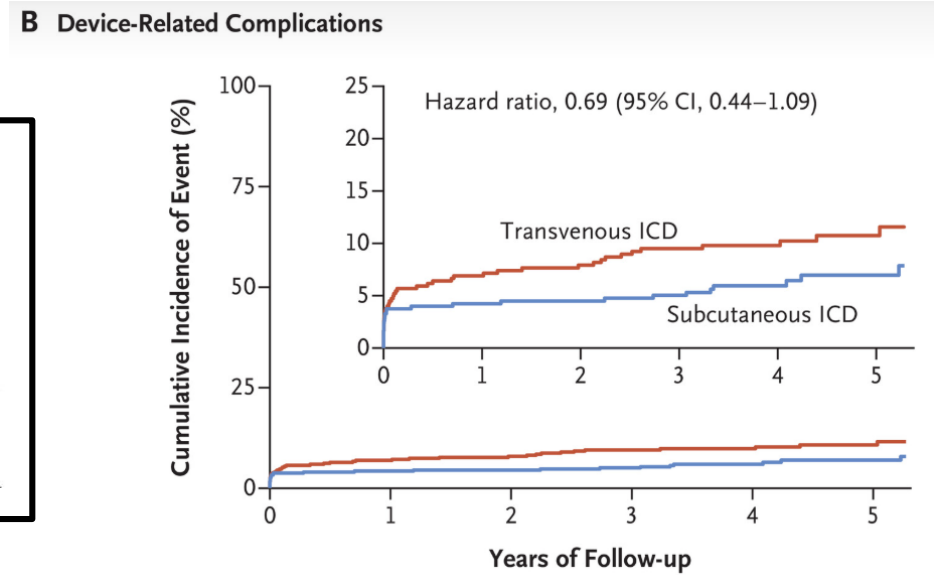


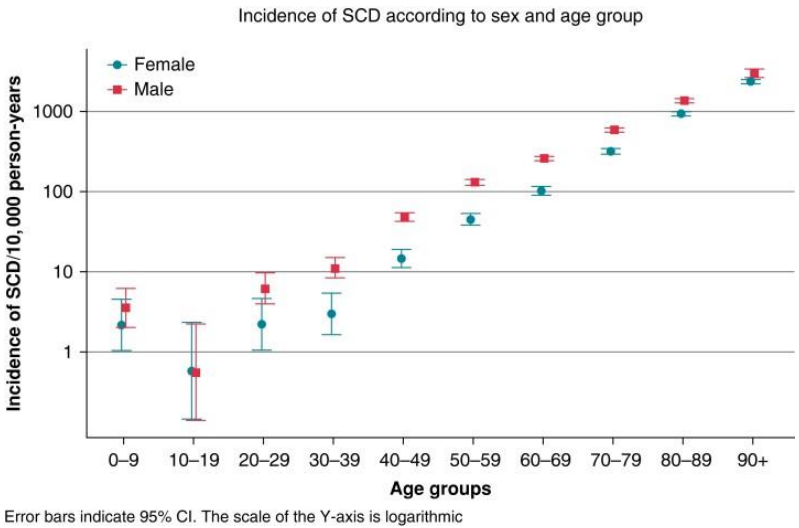
Figure 6
Four-year rates of major cardiovascular complications associated with implantable cardioverter-defibrillator (ICD) vs no ICD therapy. (Data are derived from references 48–50.)



Knops NEJM 2020

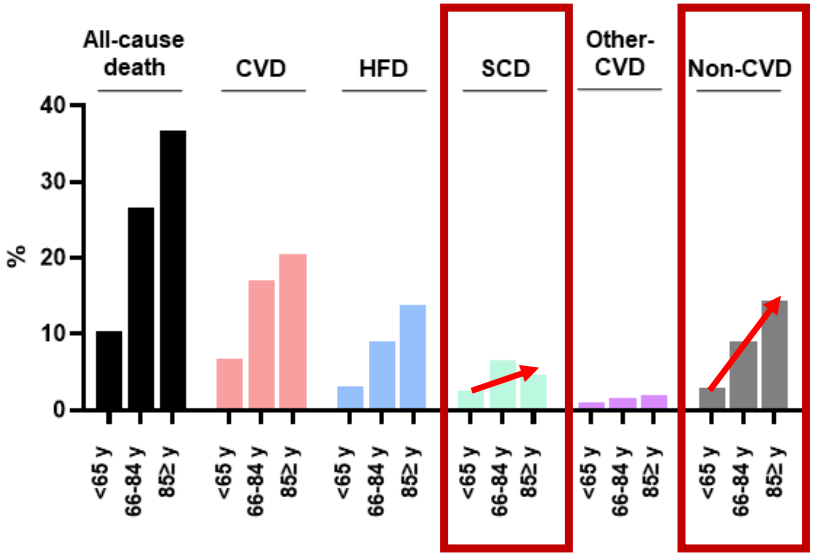
Incidence of SCD according to age

Global Population



Skjelbred T *Heart* 2022.

HF patients



Nakamaru ESC Heart Fail 2023

Iary Prevention Trials

MADIT 2

SCD-HeFT

Patients over 70 years represented only 10% of subjects in MADIT-II and SCD-HEFT

	Madit 2	SCD-HeFT
Mean Age	65 y	60 y

Effect of Age on Survival and Causes of Death After Primary Prevention Implantable Cardioverter-Defibrillator Implantation

Laurent Fauchier, MD[a,*], Eloi Marijon, MD[b,c], Pascal Defaye, MD[d], Olivier Piot, MD[e], Nicolas Sadoul, MD[f], Marie-Cecile Perier, MD[c], Daniel Gras, MD[g], Didier Klug, MD[h], Vincent Algalarrondo, MD[i], Pierre Bordachar, MD[j], Jean-Claude Deharo, MD[k], Christophe Leclercq, MD[l], Dominique Babuty, MD[a], and Serge Boveda, MD[m], on behalf of the DAI-PP Investigators[†]

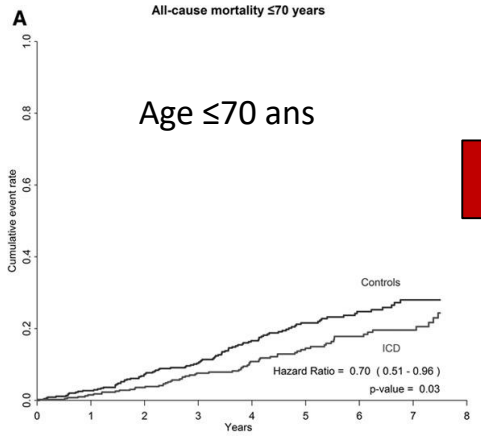
Am J Cardiol 2015

61% > 60
25% > 70
years

Table 1
Characteristics at discharge of patients with prophylactic cardioverter-defibrillator implantation

Variable*	Age group (years)			p-value
	18–59 (n=2139)	60–74 (n=2693)	≥75 (n=702)	
Age, mean (Standard deviation)	51.0 (7.5)	67.6 (4.4)	77.8 (2.4)	–
Men	1805 (84.4%)	2308 (85.7%)	585 (83.3%)	0.21
New York Heart Association functional class (n=4557)				
1	228 (13.1%)	193 (8.7%)	60 (9.9%)	<0.0001
2	821 (47.1%)	843 (38.1%)	188 (31.1%)	
3	631 (36.2%)	1084 (49.1%)	334 (55.2%)	
4	62 (3.6%)	90 (4.1%)	23 (3.8%)	
Atrial fibrillation (n=4718)	266 (14.9%)	643 (28.0%)	224 (35.1%)	<0.0001
Coronary artery disease (n=5480)	1142 (53.9%)	1701 (63.8%)	458 (65.9%)	<0.0001
QRS, ms (n=3868)				
<120	582 (40.6%)	491 (25.9%)	110 (20.2%)	<0.0001
120–150	452 (31.6%)	711 (37.6%)	204 (37.5%)	

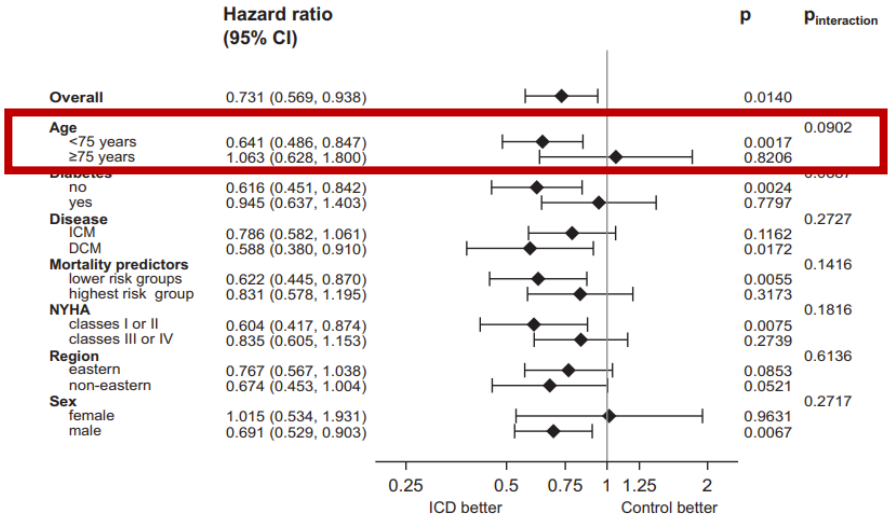
Subgroup analysis

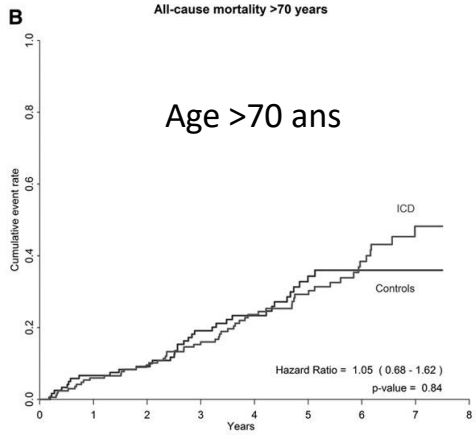


Age ≤70 ans

DANISH

EU CERT ICD





Age >70 ans

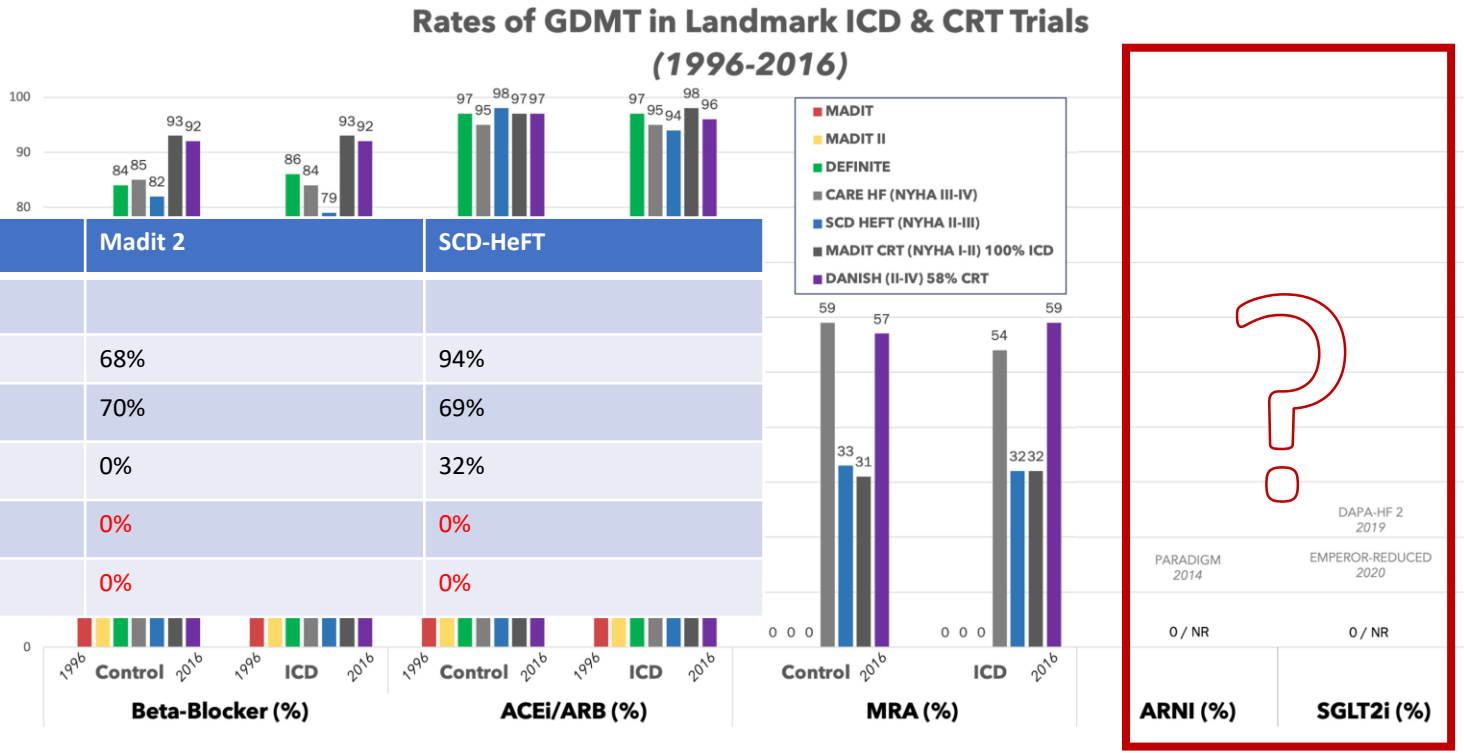
Elming
Circulation 2017

UPDATE

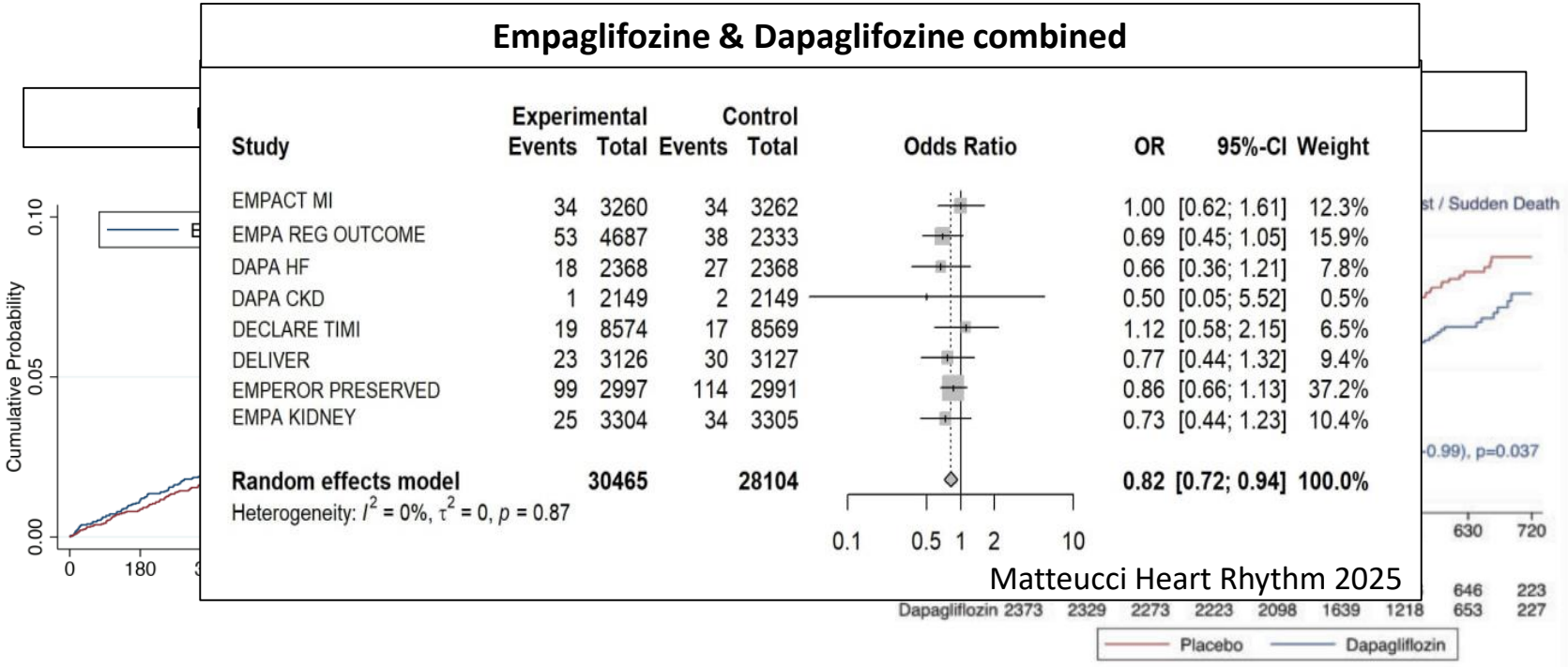
Zabel Eur Heart J 2020

HF Treatment in Landmark Trials

	Madit 2	SCD-HeFT
Traitement:		
IEC/ARA II	68%	94%
B bloquants	70%	69%
ARM	0%	32%
ARNi	0%	0%
SGLT2i	0%	0%



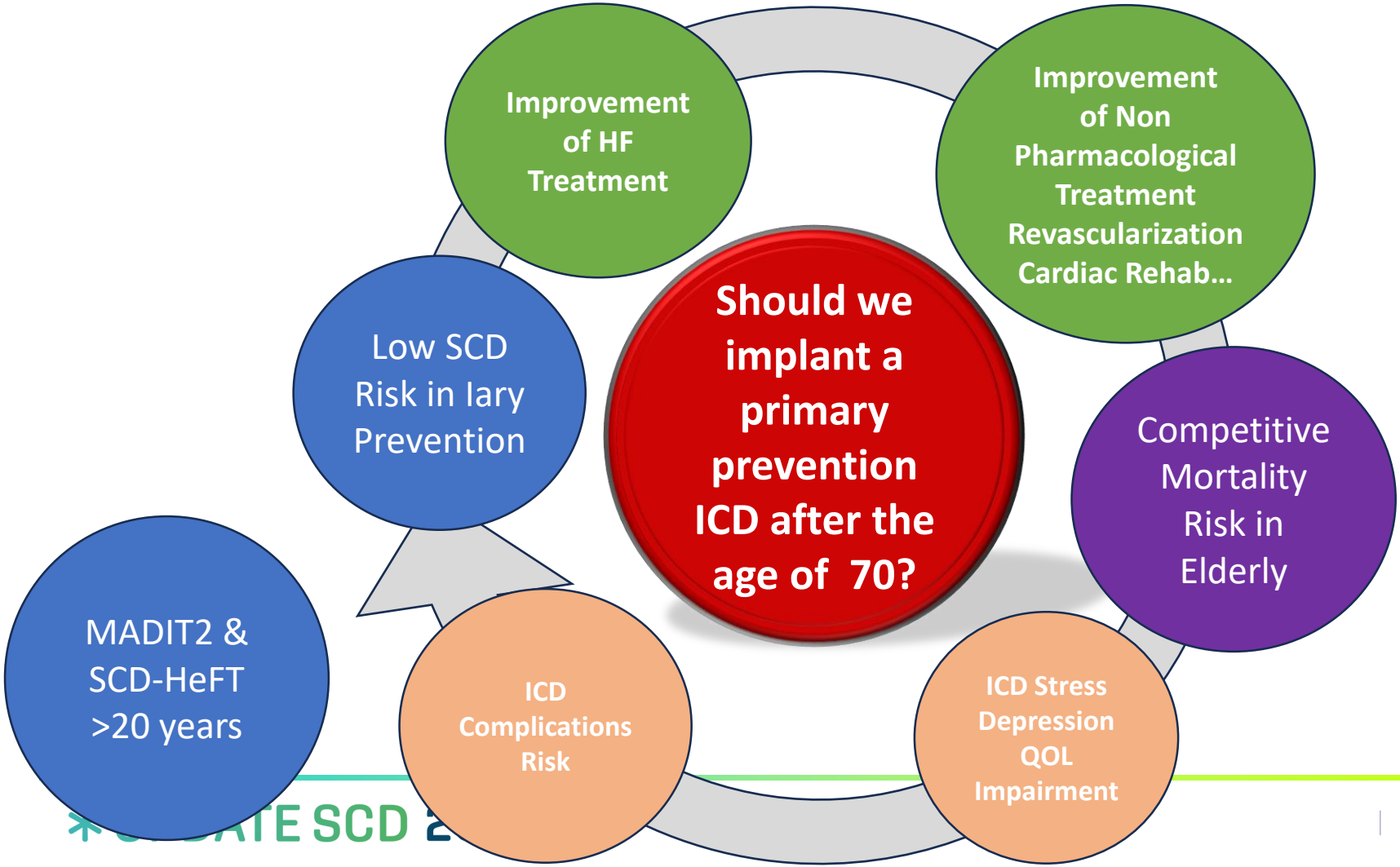
Effect of HF Treatment on Arrhythmia Risk



Matteucci Heart Rhythm 2025

Curtain *Eur J Heart Fail* 2022

	HR	95%CI
PARADIGM HF	0,79	0.65–0.97
DAPA HF	0,79	0.63–0.99


Improvement of HF Treatment
Improvement of Non Pharmacological Treatment Revascularization Cardiac Rehab…
Low SCD Risk in Iary Prevention
Should we implant a primary prevention ICD after the age of 70?
Competitive Mortality Risk in Elderly
MADIT2 & SCD-HeFT >20 years
ICD Complications Risk
ICD Stress Depression QOL Impairment

DILEMMA Study

Should we implant a primary prevention ICD after the age of 70?

PHRC-N
Programme hospitalier de recherche clinique national

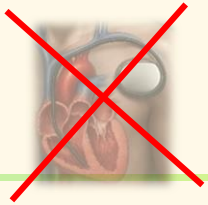
Randomized, non-inferiority, multicentric prospective Trial

+

≥ 70 years old

EF ≤ 35%

Randomization



730 patients
48 months FU

Should we implant a primary prevention ICD after the age of 70?

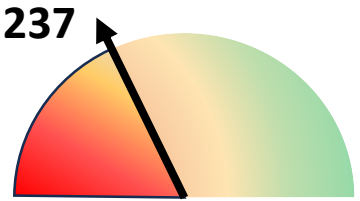
Primary Endpoint
Survival at 48 Months

QOL assessment

Health economics analysis

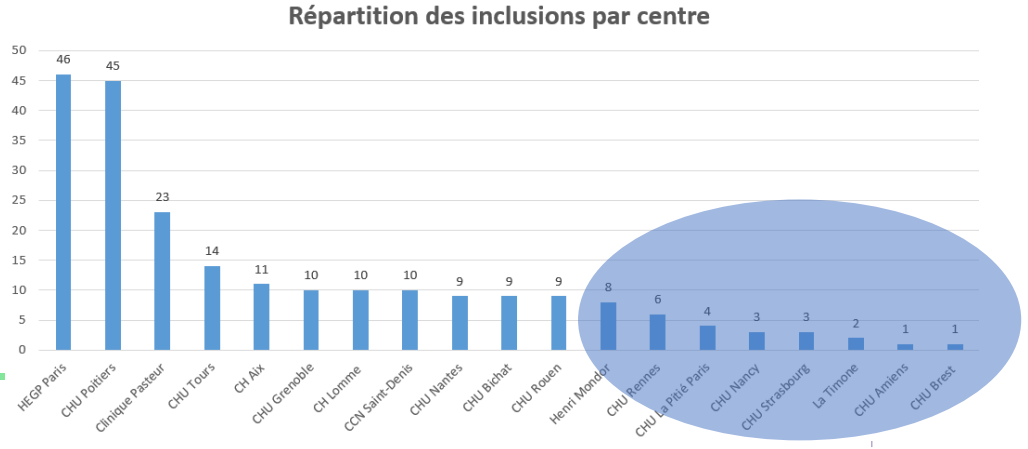
Subgroup analysis
- ICM vs NICM
- CRT vs non-CRT
- Charlson Comorbidity Index (CCI)

Inclusions



Updated Nov 2025

Total : 730



POTENTIAL & CHALLENGES

DILEMMA Trial — POTENTIALS

- DILEMMA: Is GDMT alone non-inferior to GDMT + ICD for survival at 48 months in patients ≥70 years with a lary-prevention indication?
- Impact: could support GDMT/CRT-focused strategies in many older patients, with fewer implants where net mortality benefit is marginal
- GL: this addresses the evidence gap from under-representation of elderly patients in prior ICD RCTs and could enable "aging-specific" recommendations
- Patient: shared decisions for those prioritizing quality of life, fewer procedures, and end-of-life preferences
- Health-economics: potential reduction in device-related costs, hospitalizations, and complications if non-inferiority is confirmed
- Risk-stratification: planned subgroups (ischemic vs non-ischemic, CRT-P vs CRT-D, frailty/comorbidity) can refine who truly benefits.

DILEMMA Trial — CHALLENGES

- Non-inferiority design: margin and event-rate assumptions are critical; underestimation risks a false 'non-inferiority' conclusion…
- Competing risks in the elderly: high non-arrhythmic mortality can dilute ICD effect on all-cause mortality (in fact, this is one of the goal of the trial…)
- ***Heterogeneity of aging***: frailty, multimorbidity, and cognitive status influence outcomes, complication rates, and decision quality
- Technology drift: ***CRT, CSP, and S-ICD*** adoption may confound comparisons

- And… ***inclusion rate…***